



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Castor Oil (Shaughessy No. 031608), the Active Ingredient in Mole-Med (EPA File Symbol 64439-R): Request to Concur with Recommendations for Reduced Data Requirements

FROM: Ad Hoc Screening Committee for Reduced Risk Pesticides

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TO: OPP Division Directors

This memorandum summarizes the basis for recommending reduced data requirements for Castor Oil, a biochemical pesticide that is considered the active ingredient in Mole-Med, and to request concurrence for those recommendations.

BACKGROUND INFORMATION: On Wednesday, February 17, 1993, representatives of the Ad Hoc Screening Committee for Reduced Risk Pesticides met to determine the eligibility of castor oil as a candidate for the proposed reduced data requirements. Castor oil, the active ingredient in Mole-Med, is derived from the seeds of castor beans and, according to the registrant's supplier, exceeds U.S. Pharmacopeia (USP) grade because additional refining has

removed the odor and taste from the oil. Provided that the oil meets USP grade FDA regulations (21 CFR 172.876) the subject product is allowed to be used as a direct food additive. According to the registrant the product Mole-Med acts as a mole repellent due to the possible irritant effects on moles.

DISCUSSION/CONCLUSION: In March, 1992, the OPP Biotechnology Workgroup classified castor oil as a biochemical pesticide based on certain criteria set forth in 40 CFR 158.65 (see March 3, 1992 memorandum from J. T. McClintock to R. A. Forrest/D. B. Peacock). As a biochemical pesticide, no environmental fate studies were required because the Tier I fish and wildlife testing did not demonstrate any hazards. Following a registration screen of the technical material, the Science Analysis Branch (SAB) recommended that castor oil be considered as a candidate for the reduced data requirements as outlined in the June, 1992 draft Guidance for Making Determinations to Reduce Data Requirements for certain pesticidal products. To this end, the Ad Hoc Committee convened and determined that castor oil should be a candidate for the reduced data requirements. The committee agreed that castor oil satisfied the necessary criteria as set forth in the Guidance document; and, therefore, is subject to a reduced data set. Of the criteria presented in this document, the following conditions were satisfied:

Group I Two of the three criteria were satisfied as required and as follows:

- a). Listed as GRAS (21 CFR 172.876).
- b). Widely distributed in commerce and available to the general public throughout the U.S. for nonpesticidal use.

Group II Four of four criteria were satisfied and as follows:

- a). No 6(a)2 data submitted.
- b). The Agency is not aware of any adverse effects of the active ingredient to humans or the environment in the literature when used in a manner prescribed in end-use product labeling.
- c). There have been no incidents reports.
- d). There is no indication in the literature, as provided by the registrant, that the pesticide poses adverse effects in humans or to the environment when used in a manner prescribed in end-use product labeling.

Group III Two of the four criteria were satisfied and as follows:

- a). Non-toxic mode of action for target pest.
- b). Pesticide can be presumed non-persistent based on knowledge of its composition; e.g., organic material known to be rapidly degraded in the environment to elemental constituents by normal biological, physical, and/or chemical processes that can be reasonably expected to exist where the pesticide is applied.

The Committee also discussed the proposed product label directions. The label directions for use are to "Mix one ounce of Mole-Med with each gallon of water and spray or sprinkle over entire lawn. Then, water in for about 25 minutes." The oil based nature of the

product and abundant watering indicates that runoff into aquatic habitats may occur. Other surface oils and monomolecular films have adverse effects on aquatic invertebrates and some are registered as pesticides for mosquito control. The registrant provided information that the solubility of castor oil was between 100 and 300 mg/l. The low one ounce/gallon application rate and 87% ricinoleic acid composition of castor oil indicates that effects on nontarget organisms are unlikely. However, in lieu of data to verify no adverse effects and to mitigate such risks, the Committee recommends two modifications to the proposed label as indicated below.

RECOMMENDATION: Based upon the discussion/conclusion section above, the Ad Hoc Screening Committee for Reduced Risk Pesticides makes the following recommendations about the data and labeling requirements for Castor Oil and Mole-Med:

A. Data Requirements:

1). No further toxicology, ecological effects and environmental fate data, as set forth in Part 158, are necessary or appropriate in order to complete the assessment on the pesticidal active ingredient as required under FIFRA for the purpose of registration. It should be noted that the three submitted acute toxicity studies on the technical grade material will be reviewed by SAB.

2). Acute toxicology data requirements for end-use products may be required unless an assessment of the inert ingredients in combination with the active ingredient indicates that such data are not necessary to provide appropriate labeling.

B. Labeling Modifications:

1). Modify the ENVIRONMENTAL HAZARDS for Mole-Med to read: "Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters."

2). In the use directions, change: "Then water in for 25 minutes." to "Then soak in with water for about 25 minutes. Avoid using excess water that may flow off turf into streams, ponds, gutters or storm sewers."

REQUEST TO CONCUR: If you agree with the above recommendations, please concur on the attached concurrence sheet. If you concur with comments, attach a copy of those comments to the concurrence sheet. If you do not concur, please indicate your reasons.

The Ad Hoc Screening Committee for Reduced Risk Pesticides would appreciate your response by Wednesday, March 24, 1993. If you have any questions regarding these recommendations please contact Tom McClintock (SAB/HED) at 305-7444.